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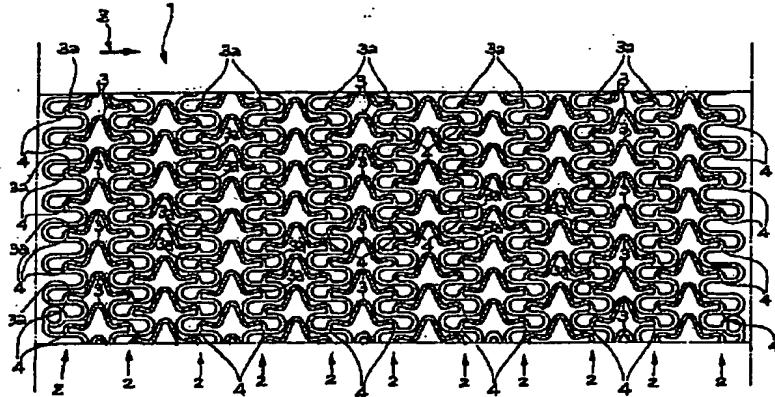
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(54) "A stent for angioplasty"

(57) A stent for angioplasty has a body (1) in the form of a generally tubular envelope susceptible of being dilated in use from a radially-contracted position into a radially-expanded position. The body of the stent (1) includes a plurality of successive segments (2) having a serpentine shape with loop parts having sequen-

tially-opposite concavity. These loop parts are connected by connector parts (4) and the bridges (3) which connect the segments (2) of the stent together join to the aforesaid connector parts (4).

FIG. 1



EP 0 875 215 A1

Description

The present invention generally concerns so-called stents for angioplasty.

This term is intended to indicate in general those devices intended for endoluminal application (for example, in a blood vessel), usually effected by means of catheterisation, with subsequent deployment in place so as to achieve local support of the lumen. The primary purpose of this is to eliminate and avoid the restenosis of the treated area. It is moreover noted that it has already been proposed in the art to use substantially similar structures in order to achieve the deployment and anchorage *in situ* of vascular grafts: naturally, this possible extension of the field of application is also to be understood as being included within the scope of the invention.

For a general review of vascular stents, reference may usefully be made to the work "Textbook of Interventional Cardiology" edited by Eric J Topol, W.B. Saunders Company, 1994 and, in particular, to section IV of volume II, entitled "Coronary Stenting".

Many patent documents have addressed this issue as shown, for example, by US-A-4 776 337, US-A-4 800 882, US-A-4 907 336, US-A-4 886 062, US-A-4 830 003, US-A-4 856 516, US-A-4 768 507, US-A-4 503 569 and EP-A-0 201 466.

Notwithstanding the extensive research and experimentation, as documented at the patent level, only a relatively small number of operative solutions have, until now, found practical application.

This is due to various factors, among which the following problems or requirements may be mentioned:

- ensuring that, while moving towards the treatment site, the stent is capable of adapting with sufficient malleability to the path taken, even as regards less curved sections such as those which may exist, for example, in some peripheral vessels; all of this without detrimentally affecting the ability of the stent to provide an effective support action once positioned and deployed;
- avoiding, or at least limiting, the longitudinal shortening effect which occurs in many stents on deployment;
- achieving the maximum homogeneity and uniformity in the expansion movement, avoiding (when this is not a required effect) a situation in which this movement manifests itself to an extent and at times which vary in different areas or sections of the stent;
- providing the wall of the lumen which is being supported with a support surface that is as extensive as possible;
- avoiding the origination of complex shapes and/or possible stagnation sites susceptible, especially in blood vessels, of giving rise to negative phenomena such as coagulation, thrombosis, etc; and

reconciling the requirements described above with the modality and criteria of simple production, reliability and the introduction of currently available technology.

The present invention, having the characteristics referred to specifically in the following claims, has the object of resolving, at least in part, the problems outlined above. To this end, the solution according to the present invention is capable of being integrated with at least some of the solutions described in the earlier European patent applications Nos. 97107423.2, 97121538.9, 97122879.6 and 98100010.2 and in the Italian patent application No. TO96A000655, all of which are assigned to the same assignee of the present application and are included in the state of the art within the meaning of Article 54 (3) EPC.

The invention will now be described, purely by way of non-limitative example, with reference to the accompanying drawings in which:

- Figure 1 illustrates, in a theoretical plane, the geometrical characteristics of the wall of a stent for angioplasty manufactured according to the invention, illustrated in the radially-contracted position;
- Figure 2 illustrates, in conditions substantially similar to those of Figure 1, that is, in the radially-contracted condition, another possible embodiment of the invention; and
- Figure 3 illustrates, also in a theoretical plane, the geometrical characteristics of the wall of the stent according to Figure 2 seen in the radially-expanded condition.

The reference numeral 1 is utilised in the drawings to indicate in its entirety a so-called stent for angioplasty.

For a general identification of the manner of use and the characteristics of this implantation device, reference should be made to the documentation listed in the introduction to the description.

By way of summary, it will be recalled that the stent 1 is usually formed as a body which is a tubular envelope generally between several millimetres and several tens of millimetres in length, and with a wall thickness (the wall usually being an apertured mesh or loop structure, as will be seen better below) of the order of, for example, several hundredths of millimetres, because of its possible insertion into a lumen (such as a blood vessel) at a site where stenosis is to be corrected. The stent is normally located *in situ* by means of catheterisation followed by radial expansion from an introduction diameter of the order of, for example, 1.5-1.8 mm, to an expanded diameter of the order of, for example, 3-4 mm such that, in this expanded condition, the stent exerts a supporting action on the lumen, eliminating and avoiding restenosis. In general, the external diameter in the radially-contracted condition is chosen so as to enable

the introduction of the stent into the lumen being treated, while the expanded diameter corresponds in general to the diameter required to be maintained in the lumen once the stenosis has been eliminated. It should also be remembered that, although the principle application of the stent described is in relation to the treatment of blood vessels, its use as a support element for any lumen present in the human or animal body can be envisaged (and is therefore included in the scope of this invention).

As regards the modality and the criteria which enable the deployment (that is, the *in situ* expansion) of the stent, currently the most widely used solution is to use a so-called balloon catheter, disposing the stent about the balloon of the catheter in the contracted condition and then expanding the balloon once the stent has been taken to the deployment site. Different solutions are also possible, such as using superelastic materials which, once the containment elements intended to hold the stent in the contracted condition until it has reached the implantation site are removed, give rise to the expansion of the stent. In addition, or alternatively, it has been suggested that materials having a so-called "shape memory" may be used so as to achieve the radial expansion in the implant position.

Usually (for more precise details, reference should be made to the bibliographic and patent documentation listed in the introduction to the description), the stent is made from a metal capable of satisfying two fundamental requirements of use, that is, the capability of plastically deforming during the expansion phase and the capability of resisting, and thus retaining the expanded shape, possible forces which would otherwise lead to the stent reclosing. The material known under the commercial name "Nitinol" has been shown to be successful both from the point of view of its superelasticity, and its shape memory which is possibly needed during the expansion phase.

In any case, these technological aspects will not be dealt with in detail in the present description in that they are not in themselves relevant to the comprehension and production of the invention. This also applies essentially to the technology for the production of the stent according to the invention. As has already been said, these stents assume, in general terms, the form of a body made from a tubular envelope with an apertured wall. As regards production, reference may be made, using known techniques, to at least three basic arrangements, which are:

- forming the stent from a continuous tubular blank intended to be segmented into individual stents, with the apertured parts being formed using techniques such as laser incision, photo-incision, electroerosion, etc;
- forming the stent from a strip-like body in which the apertured zones are formed, for example, using the techniques listed above, with the subsequent clo-

sure of the strip-like element into a tube; and
- forming the stent from metal wire shaped by the subsequent attachment of wire loops, for example, using operations of micro welding, brazing, gluing, crimping etc ...

The first arrangement described is the one currently preferred by the Applicant for producing stents according to the embodiments described below. In particular, cutting using laser beams has been shown to be the most flexible solution as regards the possibility of the rapid modification of the characteristics of the stent during production, in response to specific applicational requirements.

15 In any case, it is emphasised that even this aspect of production is not relevant, in that it is marginal, to the production of the invention. This also applies to the choice of the individual techniques and the order in which the various operations described (the production of the apertured parts, segmentation, possible folding of the strip-like element etc) are performed.

In the embodiments illustrated here, the body of the stent 1 extends longitudinally in the direction generally identified as a z-axis. For clarity, it should be remembered that the stent is intended to be folded, perhaps significantly, during use, so that good flexibility is certainly one of the required characteristics.

20 In the embodiments illustrated here, the body of the stent 1 is constituted by a series of successive segments of generally annular form, indicated 2 in the drawings.

25 In order to illustrate these ideas, without them being interpreted in a limitative sense in the context of the invention, the length of the segments 2 measured in the longitudinal direction of the stent 1, that is, along the z-axis, is of the order of approximately 2 mm (or several mm). In other words, the segments 2 are usually fairly "short".

30 The various segments of the stent 1 illustrated here are joined together by bridges 3 (which are actually integral components of the stent wall) intended to form a hinge connection between the segments 2 to enable the stent 1 to flex or bend.

35 Essentially, the longitudinal flexibility of the stent 1, necessary to assist in its location at the implantation site, is essentially due to the bridges 3, while its structural strength, that is, its support of the lumen, is due primarily to the structure of the segments 2 with the co-operation of the bridges 3 being envisaged for this purpose as seen in the embodiment of Figures 2 and 3. All this gives rise to the possibility of achieving optimisation of the desired characteristics by means of an exact adaptation of the sections of the various component elements.

40 Examining the structure of Figure 1 first of all, which is the most simple from this point of view, it can be noted that each segment 2 has a serpentine-like shape with a generally sinusoidal profile.

In the embodiment and the radially-contracted condition illustrated in Figure 2, the aforesaid serpentine-like shape assumes a more complex shape which may be seen hypothetically as being derived from the shape shown in Figure 1 due to a "squeezing" of the apex part 2a of each of the half-waves of the sinusoidal path illustrated in Figure 1 until it achieves an almost lobe-like shape.

In any case, by examining the same structure in the radially-expanded condition illustrated in Figure 3, it can be noted that the aforesaid serpentine-like shape translates, in this expanded condition, into a triangular wave shape.

Both in the embodiment of Figure 1, as well as in the embodiment of Figure 2, the segments 2 have a serpentine-like shape with successive loop parts having a generally opposite concavity.

In each segment 2, the aforesaid loop parts open alternately towards the left and right (with reference to the plane of the drawing in Figures 1 and 2) in an arrangement in which the shapes of adjacent segments 2 may be seen, as it were, as opposite in phase (that is, offset by 180°), so that the concavity of each loop faces the concavity of an adjacent segment 2, and the respective convexity faces the convexity of the adjacent segment 2 on the opposite side.

The aforesaid loop parts are connected by intermediate connector parts indicated 4.

In the embodiment of Figure 1, the aforesaid connector parts 4 correspond in practice to the crossings of the zero points of the theoretical sinusoidal path of the segments 2 and extend - when the stent is in the radially-contracted position - substantially in the longitudinal direction of the stent 1 itself, that is, along the z-axis.

In the embodiments of Figures 2 and 3, the aforesaid connector parts 4 are also generally straight and extend to connect the loop parts that are crushed or squeezed (as defined above in relation to the stent 1 in the radially-contracted condition, that is, as shown in Figure 2) in a generally oblique direction, and practically at approximately 45° with respect to the longitudinal axis z of the stent, maintaining this orientation substantially unchanged even during the radial expansion of the stent 1 so that, when the stent is expanded (Figure 3), the connector parts 4 constitute the central portions of the sides of the triangular wave profile assumed by each segment 2.

Naturally, in consideration of the alternating sequential distribution of the loop parts of the segments 2, the connector parts 4 form, with respect to the aforesaid longitudinal axis z, alternate positive and negative angles (that is, approximately +45°, -45°, +45°, -45° etc ... the sign of the aforesaid angle being in itself irrelevant, in that what counts is the inversion of the sign itself in the sequence of connector parts 4).

Even though the concept is very clear to the expert in the field, with reference to the plane of the wall of the stent 1 as shown in Figures 1 to 3, the radial expansion

of the stent corresponds (for example, the embodiments of Figures 2 and 3 illustrate both the radially-contracted and the radially-expanded positions) to a stretching of the plane represented in Figure 2 in the sense of an increase in the height, that is, a dilatation in the vertical sense, as represented in Figure 3.

An important characteristic of the arrangement according to the invention is given by the fact that the bridges 3 connect to the segments 2 not only at the loops thereof, but also at the connector parts 4 and, in particular, at a median position thereof.

Therefore, with reference to the embodiment of Figure 1, the bridges 3 attach to the segments 2 approximately in correspondence with the zero points of the respective sinusoidal paths.

Since, as has been seen above, when the stent is in the radially-contracted position, the connector parts 4 are orientated along the longitudinal axis z of the stent 1, in the embodiment of Figure 1 the bridges 3 have generally curved and extended end parts 3a at the end connected to the connector parts 4 in a theoretical transverse plane with respect to the stent 1 (that is, in a generally orthogonal plane with respect to the longitudinal axis z).

The bridges 3 preferably have a curved profile which, in the embodiments illustrated, corresponds substantially to a V-shape. The two branches of the V preferably have distal connector parts at the end regions 3a which extend in an approximately longitudinal direction (z axis) with respect to the stent 1.

The aforesaid V-shape (but a different shape of equivalent concave-convex type can equally well be used within the ambit of the present invention) enables the formation of a very strong connection between adjacent segments of the stent 1. In practice, for each sinusoidal wave of the theoretical path of the segments 2, a bridge 3 can be present for connection to the adjacent segment 2 "to the left", and another bridge 3 for connecting to the adjacent segment 2 "to the right". Naturally, in the case of the segments 2 located at the end of the stent, the above applies to the single adjacent segment 2.

From this arises the possibility of conferring on the wall of the stent 1, which is naturally apertured, a very dense and extremely uniform reticular structure.

In this sense, it can be useful if, for example, in the embodiment of Figure 1, the rigid parts (that is, in the example illustrated, the V-shape parts) of the bridges 3 are all orientated with their convexity (or concavity) facing in the same direction, so as to enable the possible co-penetration of the extensions of adjacent bridges 3 (that is, with the convex part of one of the bridges 3 penetrating the concave part of the adjacent bridge 3, and thus going beyond the condition of overall tangency adopted in the embodiment shown by way of example in Figure 1).

In any case, it appears possible to adopt a different solution, for example, with the bridges 3 having their

concavity/convexity facing in opposite directions in alternate sequence. As in the case of practically all the other sequences referred to in the present description and in the following claims, it is not necessary to think of an alternating sequence with a single step, as the sequence can be different: for example, two-step, with two bridges 3 having their concavity facing in one direction, followed by two bridges with their concavity facing in the opposite direction, etc; the entirety following a theoretical path along the circumference of the stent 1.

The embodiment of Figures 2 and 3 actually adopts a bridge structure 3 having a general V-shape, single step alternating sequence, with the concavity/convexity of adjacent bridges 3 alternating in the sense of a theoretical path along the periphery of the stent 1.

Due to the generally oblique or inclined orientation of the connector parts 4, the bridges 3 of the embodiment of Figures 2 and 3 also have their respective end parts 3a orientated, for example, at an angle of approximately 45°, with respect to the longitudinal axis z of the stent.

This is because the aforesaid end parts 3a connect at the connector parts 4 which extend obliquely, with the terminal parts 3a of the bridges orientated substantially at right angles (that is, at approximately 90°) with respect to the direction in which the connector parts 4 lie.

Looking at the alternating arrangement of the connector parts 4 (for example, in the sequence +45°, -45°, etc with respect to the z-axis), the end parts 3a of the bridges 3 in Figures 2 and 3 show a corresponding orientation.

In general, the bridges 3 connect the same connector parts 4 of a given segment 2 to the immediately adjacent segments which extend between them in a substantially co-linear position.

Consequently, in the zones in which the said corresponding bridges attach to the same connector part 4, there is formed a cruciform configuration the arms of which (two constituted by the connector parts 4 and the other two formed by the end parts 3a of the bridges 3 which are joined thereto) are orientated obliquely, usually at approximately 45°, with respect to the longitudinal axis z of the stent.

This configuration and orientation of the aforesaid crosses is maintained practically unchanged during the passage of the stent from the radially-contracted position (Figure 2) to the radially-extended position (Figure 3).

To this spatial disposition (maintained during the expansion of the stent) of the cruciform parts is added the fact that, as in the embodiment of Figure 1, the loop parts of the segments 2 are orientated, in adjacent segments 2, with sequential opposite concavity (or phase opposition, as already said above). Therefore wherever a particular segment 2 has a concavity, the adjacent segment 2 on one side also has a concavity while, wherever the first segment 2 under consideration has a

convexity, the adjacent segment 2 on the opposite side also has a convexity.

During radial expansion of the stent from the contracted condition illustrated in Figure 2 to the expanded position illustrated in Figure 3, the wall of the stent passes from the "clover-leaf" configuration theoretically recognisable in Figure 2 to the reticular structure shown in Figure 3 in which the stent wall may theoretically be seen as constituted by a succession of approximately quadrangular closed loops (although with a mixilinear outline), each having a greater dimension, with each loop joining peripherally with four adjacent loops having their greater dimensions orientated at right angles. The connection between adjacent loops occurs at portions of the wall orientated generally at an angle (that is, substantially 45°) to the direction of the longitudinal axis z of the stent.

It is, however, clear that the above detailed description applies to all aspects of the segments 2 and to the bridges 3 included in the body of the stent 1, while in the case of the two segments 2 at the ends of the stent, it is clear that these only have a single adjacent segment 2.

From the embodiment of Figure 1 can be derived, for example, the fact that the bridges 3 are only present, in the case of the segments 2 at the end positions, in correspondence with the loops the concavity of which faces the interior of the stent, as it is not necessary to provide bridges in correspondence with the loops the concavity of which faces the exterior of the stent 1 itself.

The same discussion applies equally to the embodiments of Figures 2 and 3 in which the end portions 3a of the bridges 3 attached to a segment 2 situated at the end position connect with the corresponding connector parts 4, not in a general cruciform conformation, but in a T-shape.

From comparison of Figures 2 and 3, it can easily be noted that these T-shape connection zones, just like the cruciform connector parts present in the body of the stent 1, are not subjected to any appreciable rotation when the stent 1 is deployed from the radially-contracted position to the radially-extended position.

Experiments conducted by the Applicant show that this absence of rotation of the connector parts, with a consequent maintenance of the spatial orientation and geometry of the relative zones during the radial expansion of the stent, is advantageous from various points of view, particularly as regards achieving the most regular and uniform expansion possible.

In general, both in the embodiment of Figure 1 and in the embodiment of Figures 2 and 3, the expansion of the stent 1 does not cause appreciable variation in the length (that is, along the z-axis) of the stent 1 itself.

This is because the aforesaid expansion movement affects primarily the loops of the segments 2, while not only are the bridges 3 which substantially define the length of the stent 1 not affected appreciably by the expansion movement, but they connect to the segments 2 precisely in correspondence with the connector parts

4. These constitute, in relation to the segments 2, parts that are not subjected to appreciable movements during the radial expansion of the stent.

Naturally, the principle of the invention remaining the same, the details of construction and the embodiments may be widely varied with respect to those described and illustrated, without by this departing from the ambit of the present invention.

Claims

1. A stent for angioplasty including a body (1) in the form of a generally tubular envelope capable of being dilated from a radially-contracted position to a radially-expanded position, characterised in that:

- the said body includes a plurality of successive segments (2) having a serpentine-like shape with opposite loop parts in sequence; the said loop parts being connected by connector parts (4); and
- the said successive segments (2) are connected to each other by bridge elements (3) joined to the aforesaid connector parts (4).

2. A stent according to Claim 1, characterised in that the said loop parts are opposite each other in the sequence of the said successive segments (2).

3. A stent according to Claim 1 or Claim 2, characterised in that the said bridge elements (3) have an inflexible median portion.

4. A stent according to Claim 3, characterised in that the said bridge elements (3) have a general V-shape.

5. A stent according to Claim 3 or Claim 4, characterised in that the said bridge elements (3) are convex along the periphery of the stent.

6. A stent according to Claim 3 or Claim 4, characterised in that the said bridge elements (3) have opposite, sequential convexity along the periphery of the stent.

7. A stent according to any preceding claim characterised in that:

- when the stent (1) is in the radially-contracted position, the said connector parts (4) extend in a generally longitudinal direction (z) with respect to the stent (1); and
- the said bridge elements (3) have end parts (3a) which, when the stent (1) is in the radially-contracted position, extend in a transverse direction with respect to the stent (1) itself.

8. A stent according to any of the preceding Claims 1 to 6, characterised in that the said connector parts (4) extend in a generally oblique direction with respect to the longitudinal axis of the stent (1) and are substantially unchanged following the dilatation of the stent (1) from the said radially-contracted position to the said radially-expanded position.

9. A stent according to Claim 8, characterised in that the said bridge elements (3) have end parts (3a) joined to the said connector parts (4) in a generally oblique direction with respect to the longitudinal axis of the stent (1), these also being substantially unchanged following the dilatation of the stent (1) from the said radially-contracted position to the said radially-expanded position.

10. A stent according to any of Claims 1, 8 or 9, characterised in that at least some of the said connector parts (4) are joined associated pairs of bridge elements (3) connecting successive segments (2) in the said plurality in a general cross-shape.

11. A stent according to any preceding claim, characterised in that, in the said radially-contracted position, the said loop parts have apex parts (2a) which extend along an approximately lobe-shape path.

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FIG. 1

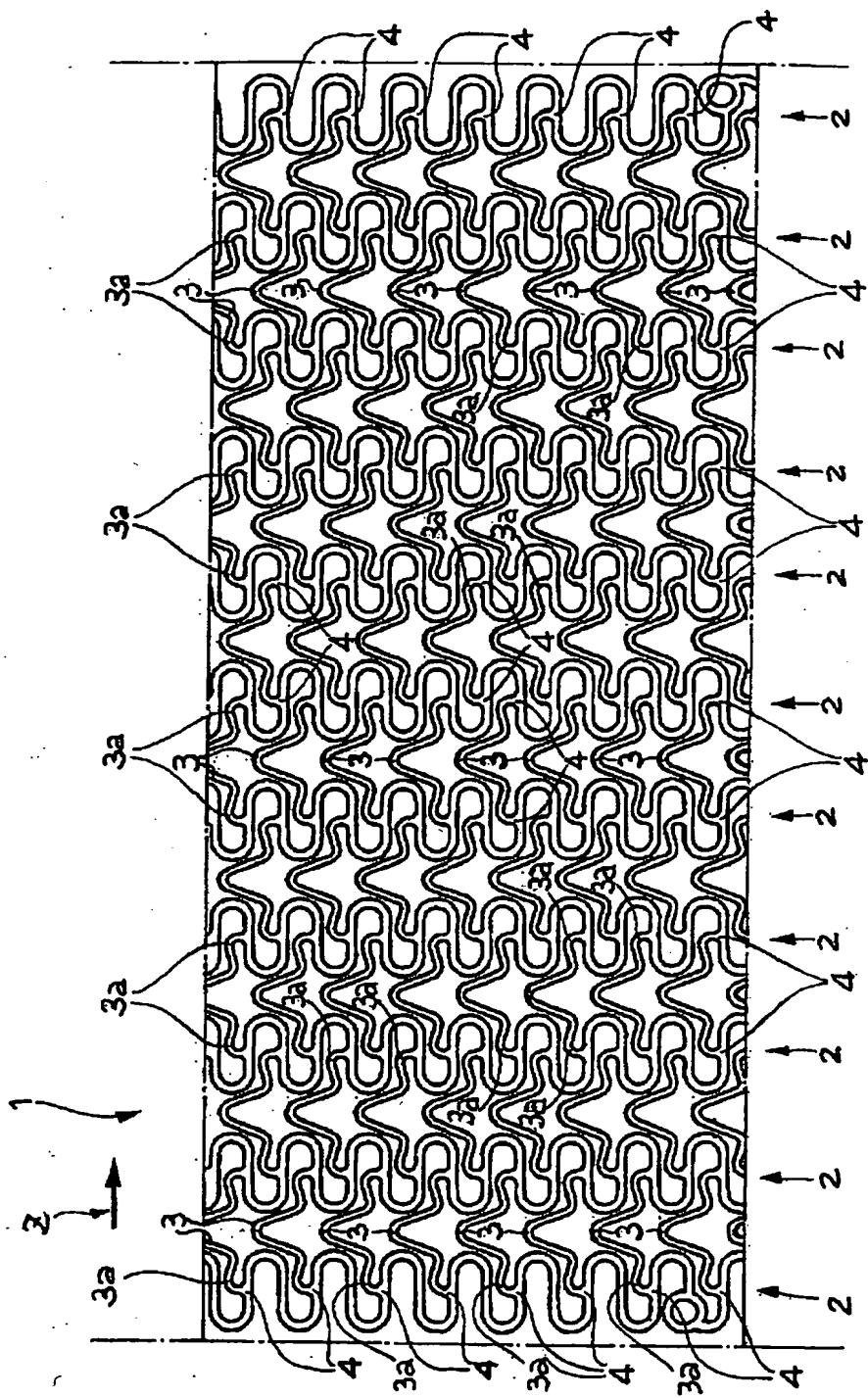


FIG. 2

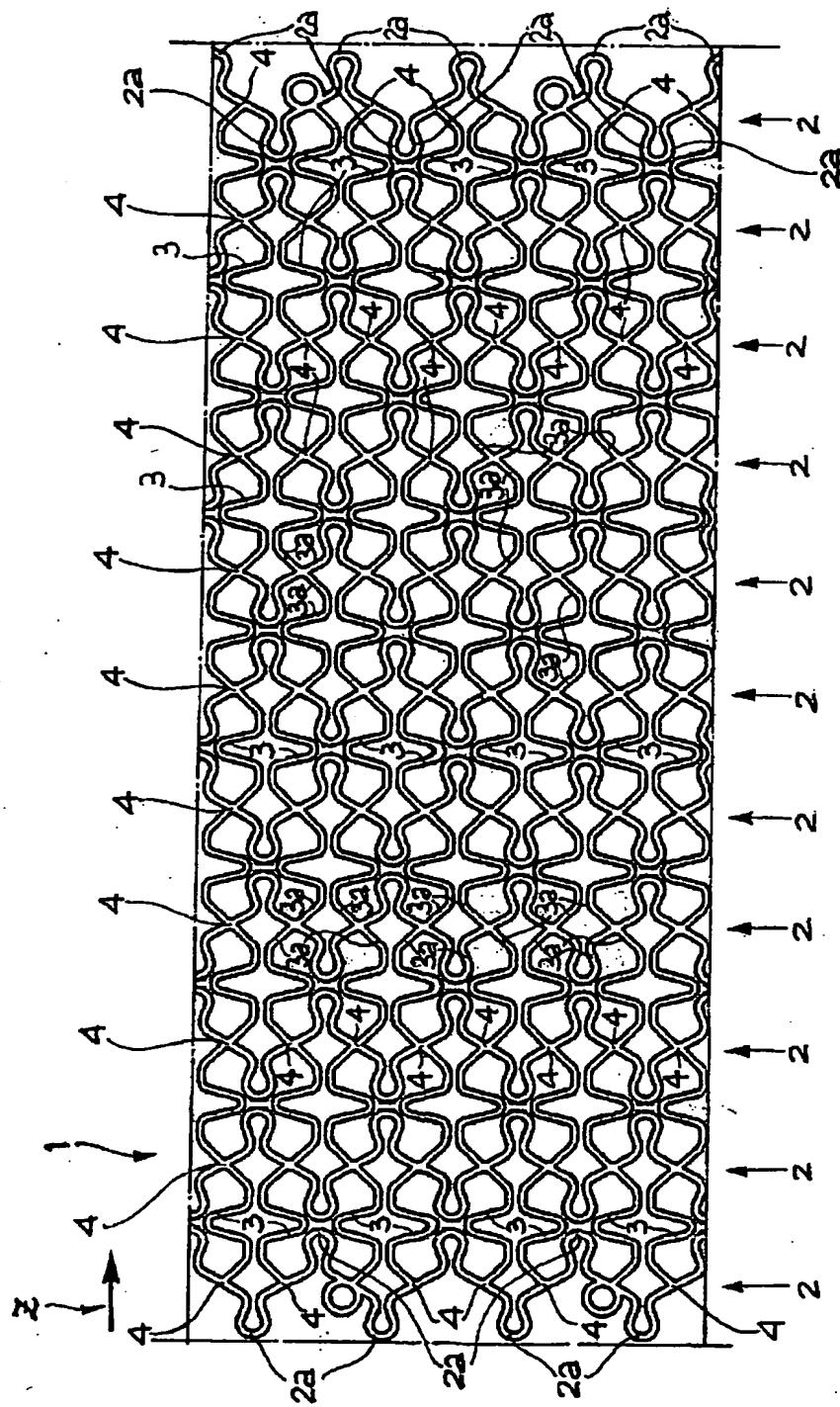
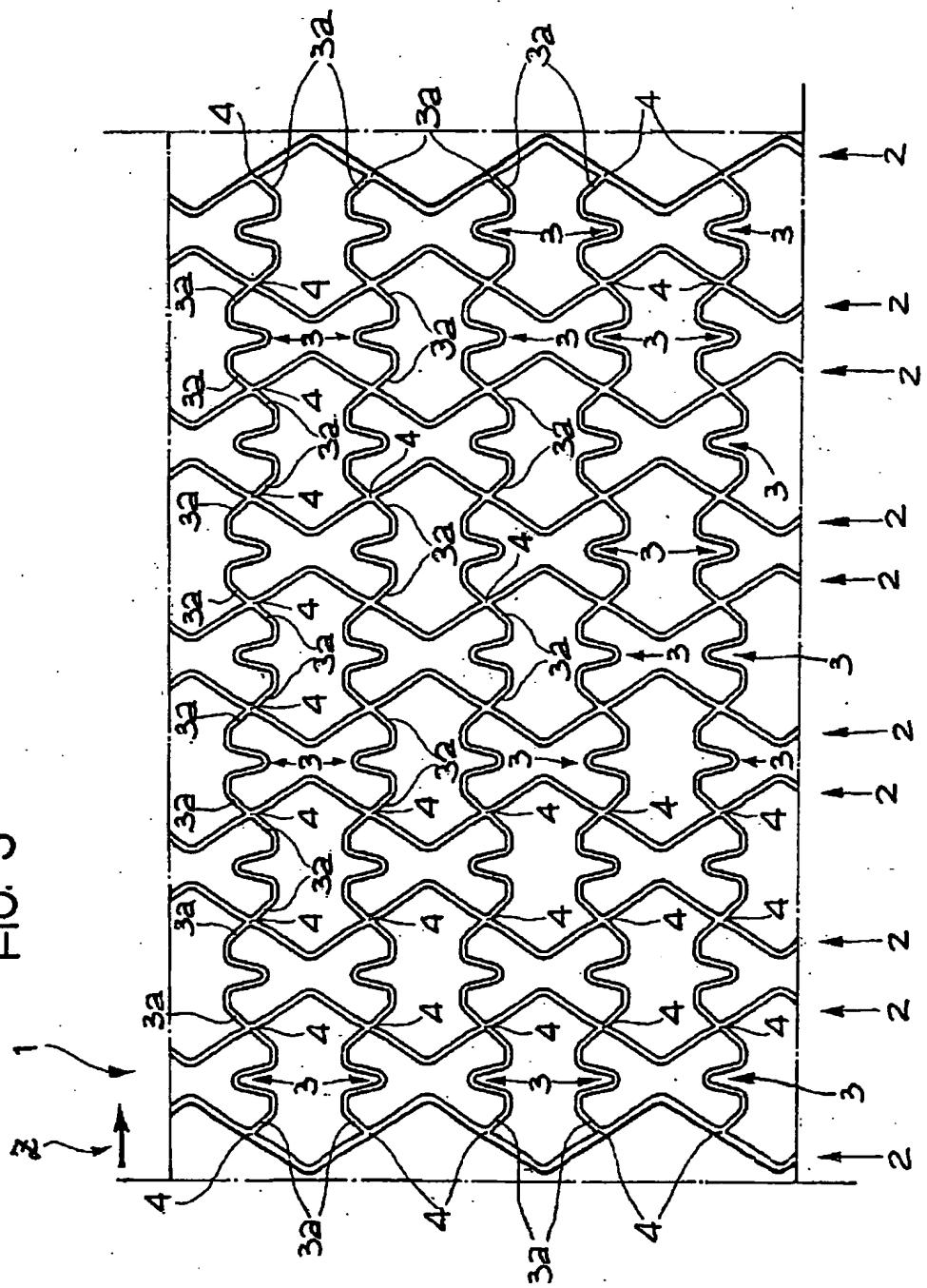


FIG. 3





European Patent
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EUROPEAN SEARCH REPORT

Application Number
EP 98 10 7382

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.)
X	DE 297 02 671 U (JOMED IMPLANTATE GMBH) 10 April 1997 * figures 2A-B * * figures 3,5,9 * * page 4, line 25 - page 7, line 10 *	1-11	A61F2/06
X	WO 96 03092 A (MEDINOL LTD ;BRUN HEIDI M (IL)) 8 February 1996 * figures 7,8 * * page 7, line 31 - page 8, line 15 *	1-6,8	
X	DE 297 01 758 U (JOMED IMPLANTATE GMBH) 27 March 1997 * figure 3 * * page 4, line 26 - line 31 *	1-6,8	
TECHNICAL FIELDS SEARCHED (Int.Cl.)			
A61F			
The present search report has been drawn up for all claims			
Place of search	Date of completion of the search	Examiner	
THE HAGUE	28 August 1998	Mary, C	
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T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			